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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,296	02/06/2006	Narayanan Badri Viswanathan	RLL-310US	8748

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RANBAXY INC.
INTELLECTUAL PROPERTY DEPT.
600 COLLEGE ROAD EAST
SUITE 2100
PRINCETON, NJ 08540

EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,296	VISWANATHAN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 5- 10, 18, 29, 35, 37* is/are pending in the application.

4a) Of the above claim(s) *29,35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5 - 10, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in the reply filed on May 6, 2009 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claim Interpretation

2. Claim 6 recites a Markush group of pharmaceutically acceptable excipients that is present in the tablet. Claims 7 – 9 further defines the various items listed in the Markush group of claim 6 but does not require that one of the items listed in each claim be present in the formulation.

Claim Rejections - 35 USC § 112 - 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the term "one or more non-

functional layers surrounding the tablet". The specification does not define this term but provides an example of a layer comprising a cosmetic coating. However, "non-functional layer" could also encompass layers which do not contain an active ingredient and therefore are nonfunctional in providing the pharmaceutical ingredient but may alter the release of the active ingredient present in other layer(s). Please clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5 – 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayer et al. (US 6,096,339).

Ayer et al. discloses a composition comprising the active ingredient verapamil hydrochloride, hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC; col 6, ln 17 – 36). Also present in this dosage form is the binder polyvinylpyrrolidone (col 6, ln 21) and the lubricant magnesium stearate (col 6, ln 23). Alfuzosin can be the drug delivered by the dosage form (claim 16).

Where selection of one named species from a list of alternatives, in this case the drug selected for inclusion in the dosage form, is all that is required to arrive at the

instantly claimed subject matter, that species is anticipated. *Ex Parte A.*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). See also *In re Sivaramakrishnan*, 213 USPQ 441 (CCPA 1982).

Layers which do not contain active ingredient (the subcoating layer and outer wall) are present and therefore meet the limitation of claim 18 which requires a nonfunctional layer to be present.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 5- 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al. (US 6,096,339).

Ayer et al. discloses a composition comprising the active ingredient verapamil hydrochloride, hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC; col 6, ln 17 – 36). Also present in this dosage form is the binder polyvinylpyrrolidone (col 6, ln 21) and the lubricant magnesium stearate (col 6, ln 23).

Ayer et al. does not explicitly prepare a dosage form comprising alfuzosin, HPMC and HPC.

Ayer et al. discloses that a variety of drugs, including alfuzosin, can be delivered in the dosage form (claim 16).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition of active ingredient, HPMC and HPC and to use alfuzosin as the active ingredient as Ayer et al. discloses alfuzosin as a suitable active ingredient for inclusion in the dosage form. Layers which do not contain active

ingredient (the subcoating layer and outer wall) are present and therefore meet the limitation of claim 18 which requires a nonfunctional layer to be present.

11. Claims 1, 5 - 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maggi et al. (US 6,149,940).

Maggi et al. discloses two or three layer tablets wherein layer 2 contains alfuzosin hydrochloride with hydrophilic polymers and a first layer and optional third layer containing hydrophilic polymers. These hydrophilic excipients are preferably chosen from the group of "super disintegrants" comprising polyvinylpyrrolidone, HPC and HPMC (col 3, ln 21 – 25) but other hydrophilic polymers such as ethyl cellulose can also be used (col 3, ln 9). The layer contains 1% to 50%, but more preferable 10% - 30% by weight of the layer of these substances (col 3, ln 29 - 30). Diluents, lubricants and binders can be included in the compositions (col 3, ln 47 – 66). In example 1 (col 5, ln 11 – col 6, ln 46), a formulation is prepared which comprises, based on the total weight of the three layer tablet, 58% HPMC and 3.7% of the hydrophilic polymers ethyl cellulose and polyvinylpyrrolidone. Also present are the diluent microcrystalline cellulose and the lubricants magnesium stearate and colloidal silica (silicon dioxide).

Maggi et al. does not explicitly prepare a dosage form comprising alfuzosin, HPMC and HPC.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an alfuzosin composition as described by Maggi et al. comprising alfuzosin, HPMC and to replace the polyvinylpyrrolidone and ethyl cellulose

with the functionally equivalent HPC polymer. The amount of these substances and the relative amounts of the different substances will affect the swelling properties of the layer and therefore the drug release from the table. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results.

12. Claims 1, 5 – 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maggi et al. (US 6,149,940) further in view of Remington The Science and Practice of Pharmacy p 894 (2000).

As discussed in greater detail above, Maggi et al. discloses multi-layer tablets comprising alfuzosin, and hydrophilic polymers such as HPMC and HPC.

Maggi et al. does not disclose the addition a nonfunctional layer to the composition.

Remington discloses that there are many reasons to add coatings to tablets that are already functionally complete, including protection from the environment, increasing ease of ingestion, improving product identity and improving product appearance (p 894, col 1, ¶ 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a layer on the tablet which does not deliver drug or affect

drug release to the multilayer tablet taught by Maggi et al. The person of ordinary skill in the art would have been motivated to do so and reasonably would have expected success as Remington discloses that such nonfunctional coatings can be applied to oral dosage forms for esthetic reasons and provide a number of advantages, such providing product identity and improved appearance.

13. Claims 1 and 5 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordes et al. (FR 2820319; all citations from US 2004/0115259).

Bordes et al. discloses composition that contains only a mixture of alfuzosin hydrochloride and HPMC that is compressed into a tablet (¶ [0038]). Excipients to modify the kinetics of release such as hydroxpropylcellulose can be included (¶ [0074]). Diluents such as lactose, mannitol or microcrystalline cellulose (¶ [0075]), the binder gelatin (¶ [0077]), and lubricants/glidants including colloidal silica (¶ [0078]) can also be included in the composition.

Bordes et al. does not explicitly prepare a composition comprising alfuzosin hydrochloride, HPMC and HPC.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising alfuzosin hydrochloride, HPMC and HPC. The person of ordinary skill in the art would have been motivated to do so and reasonably would expect success because Bordes et al. teaches that the addition of HPC to the composition will modify the release kinetics of the composition. The amount of a specific ingredient in a composition is clearly a result effective parameter

that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results.

14. Claims 1 and 5 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordes et al as applied to claims 1 and 5 – 10 above, and further in view of Lowey (US 4,259,314).

Bordes et al. discloses alfuzosin hydrochloride dosage forms with HPMC as the carrier that provides for sustained release of the alfuzosin. "Small proportions" of HPC can be added to modify the release kinetics (¶ [0074]) as well as other excipients such as binders or diluents can also be included (¶¶ [0075] – [0078]).

Bordes et al. does not explicitly specify the amounts of HPC that can be included in the composition.

Lowey discloses a long acting pharmaceutical carrier comprises of 80 – 95% HPMC and 20 to 5% HPC (col 2, ln 68 – col 3, ln 3). This material provides a controlled, long acting formulation that can be easily and inexpensively prepared with a uniform and continuous dissolution over prolonged period of time that can be used with hygroscopic and non-hygroscopic active ingredients (abstract; col 2, ln 16 – 22).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an alfuzosin tablet as disclosed by Bordes et al. and to use

a combination of HPMC and HPC as the controlled release carrier. The person of ordinary skill would be motivated to do so and reasonably would expect success as Bordes et al. discloses that HPC can be included in the composition and Lowey discloses that such a carrier is an effective sustained release material that can be used with medicaments, particularly those that are hygroscopic.

15. Claims 1, 5 – 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordes et al. as applied to claims 1 and 5 – 10 above, and further in view of Remington the Science and Practice of Pharmacy (2000).

Bordes et al. discloses alfuzosin hydrochloride dosage forms with HPMC and HPC as the carrier that provides for sustained release of the alfuzosin. Other excipients such as binders or diluents can also be included (¶¶ [0075] – [0078]).

Bordes et al. does not disclose the addition of a nonfunctional layer to the tablet.

Remington discloses that there are many reasons to add coatings to tablets that are already functionally complete, including protection from the environment, increasing ease of ingestion, improving product identity and improving product appearance (p 894, col 1, ¶ 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a layer on the tablet which does not deliver drug or affect drug release to the alfuzosin tablet taught by Bordes et al. The person of ordinary skill in the art would have been motivated to do so and reasonable would have expected success as Remington discloses that such nonfunctional coatings can be applied to oral

dosage forms for esthetic reasons and provide a number of advantages, such providing product identity and improved appearance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/

Primary Examiner, Art Unit 1618

NMW